



N-METHYLPYRROLIDONE PRODUCERS GROUP, INC.

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January 21, 2020

Via Document Submission

Document Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Re: Comments on Draft Risk Evaluation for N-Methylpyrrolidone
(EPA-HQ-OPPT-2019-0236)

Dear Sir or Madam:

The N-Methylpyrrolidone (NMP) Producers Group submits this letter and the appended documents as a follow-up to its communication with U.S. Environmental Protection Agency (EPA) staff on December 20, 2019. In that communication, which is appended to this submission, the NMP Producers Group provided an alternative approach that we believe is a viable solution for addressing study report protection under the Toxic Substances Control Act (TSCA). While EPA has not yet responded to our proposed approach, we are proceeding with the expectation that the approach will be viable and are submitting documents for both study reports requested by EPA. We are doing so to ensure that this information will be considered as comments submitted within the specified deadline for the draft NMP risk evaluation.

As reiterated in various communications with EPA, the NMP Producers Group's interest in protecting its proprietary interests in sponsored studies is not unique. We understand that other industry groups engaged in TSCA actions have expressed to EPA similar concerns with respect to study report protection.

EPA has acknowledged that it has discretion with regard to the release of study reports submitted under TSCA. EPA has further stated its view that full study reports must be made publicly available to ensure that stakeholders have sufficient information to make meaningful and informed comments.

We believe there is another approach that fairly balances the interests of data owners and stakeholders' interest in commenting on the study, which is to provide the *relevant raw data* from the study and the *robust study summary*. The totality of this information, the raw data and the robust summary, should be more than sufficient for EPA and other stakeholders to assess the quality of the studies and the conclusions reached and to facilitate the submission of informed comments. This approach also protects the study report itself from public dissemination



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and provides publicly relevant information to those with the requisite expertise to provide meaningful and informed judgments on the study results.

To support this important dialogue while protecting and in no way relinquishing the proprietary interests of NMP Producers Group members in these study reports, we hereby submit to the docket the robust study summaries and raw data for the two studies of interest to EPA:

- NMP Producers Group. (1999a). Two Generation Reproduction Toxicity Study with N-Methylpyrrolidone (NMP) in Sprague-Dawley Rats: Administration in the Diet. (Project No. 97-4106). East Millstone, NJ: Huntingdon Life Sciences, unpublished report.¹
- NMP Producers Group. 1999b. Two Generation Reproduction Toxicity Study with N- Methylpyrrolidone (NMP) in Wistar Rats: Administration in the Diet. (Project No. 70R0056/97008). Ludwigshafen, Germany: Department of Toxicology of BASF Aktiengesellschaft.

We look forward to EPA's response to this submission.

Respectfully submitted,

Kathleen M. Roberts
NMP Producers Group Manager

Attachments

¹ The robust study summary and raw data from this report were already provided to EPA in the December 20, 2019, NMP Producers Group communication, but they are being re-submitted so that they become part of the public comment record.